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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/761,201	01/22/2004	Thomas Boren	0825-0176P	3104

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EXAMINER	
PORTNER, VIRGINIA ALLEN	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 03/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/761,201	BOREN ET AL.	
	Examiner	Art Unit	
	Ginny Portner	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 November 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16,19 and 22-30* is/are pending in the application.

4a) Of the above claim(s) *1,9-15 and 22-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-8,16,19 and 27-30* is/are rejected.

7)☒ Claim(s) *4-8,16,19,29-30* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/16/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-16, 19, 22-30 are pending.
Claims 2-8, 16, 19, 27-30 are under consideration.
Claims 17-18 and 20-21 have been canceled.
Claims 1,9, 10-12,13,14-15, and 22-26 stand withdrawn from consideration.
1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. ***Rejection Withdrawn, Claim Rejections - 35 USC § 101:*** Claim 3 and 6 have been amended to recite the phrase "isolated", thus obviating the rejection
2. ***Rejection Withdrawn: Double Patenting*** Claims 17-18 objected to under 37 CFR 1.75 as being a substantial duplicate of claim 16 and claim 3 has been obviated through cancellation of the claims.
3. ***Rejection Withdrawn: Double Patenting*** Claims 20-21 objected to under 37 CFR 1.75 as being a substantial duplicate of claim 19 and claim 6 has been obviated through cancellation of the claims.
4. ***Rejections Withdrawn Claim Rejections - 35 USC § 102:*** Claims 3-8, 16, 19 rejected under 35 U.S.C. 102(b) as being anticipated by Boren et al (1995), in light of the amendment of the claims to recite the term "monospecific".

5. ***Rejections Withdrawn/ Claim Rejections:*** The rejection of claim 3-8 and 16, 19 under 35 U.S.C. 102(b) as being unpatentable over Alemohammad (US Pat. 5,262,156) as evidenced by Bai et al (2004) is herein withdrawn in light of the claims having been amended to recite the term "monospecific". The term "monospecific" having the meaning: reacting with a single antigen, as a monospecific antiserum.

6. ***Rejections Withdrawn Claim Rejections - 35 USC § 103*** Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Alemohammad (US Pat. 5,262,156) in view of Foster et al (US Pat. 4,444,879), in light of the amendment of the claims to recite the term "monospecific".

Response to Arguments

7. Applicant's arguments filed November 16, 2005 have been fully considered but they are not persuasive.

1. ***Rejections Maintained Claim Rejections:*** The rejection of claims 3-8, 16, 19 and new claims 27-30 under 35 U.S.C. 102(b) as being anticipated by Durrant et al (1993) is traversed on the grounds that:

- (Remarks page 12, first paragraph) the anti-idiotypic antibody that presents Lewis B antigen may not bind to BabA: "there is no guarantee that this will occur";
- (Remarks page 12, second paragraph) Aguius et al is cited as evidence and Applicant asserts that based upon Aguius et al asserts: "The results indicate that the antigen and its anti-idiotypic antibody do not bind to overlapping sites on the antibody" and concludes that the anti-idiotypic Lewis b antibody applied against the claims would not necessarily bind to BabA.

2. It is the position of the examiner that the chemical structure of choline (Aguius et al's antigen) and Lewis B antigen are different. It is also the position of the examiner that human acetylcholine receptor protein of Aguius et al is not analogous to BabA antigen as the two molecules do not evidence the same or equivalent molecular structure.

In support of the examiner's position, that the anti-idiotypic antibody which evidences the Lewis B antigen structure disclosed in Durrant et al would bind to BabA protein that binds to Lewis B antigen, Essery et al (1994) is being sited to show an anti-idiotypic Lewis antibody that binds to Helicobacter pylori. Essery et al disclose that 1 of 3 strains of Helicobacter pylori bound to the anti-id Lewis A IgG monospecific antibody (see Essery et al abstract, page 16, col. 2, paragraphs 3-4; and page 19, col. 2, paragraph 1 "Specificity of the protein A Sepharose reagent" that comprised the anti-idiotype antibody that bound to anti-Lewis A antibodies) which was also evidenced specific binding to and reactivity with anti-Lewis B antibodies (see page 19, col. 2, paragraph 1).

The anti-idiotypic antibody which presents a Lewis antigen conformation was found to bind to H.pylori, wherein the antibody also evidenced binding to an antibody to Lewis-B antigen. Therefore, the anti-idiotypic Lewis B antigen presenting polyclonal antibody of Durrant et al would specifically bind to BabA antigen, which binds to Lewis B antigen. Essery et al (1994)

provides evidence that H.pylori will bind to anti-idiotypic antibodies that present Lewis antigen conformations, the anti-idiotypic antibody evidencing specific binding to anti-Lewis B antigen antibodies, and therefore would be specifically bound by BabA which also binds Lewis B antigen.

Durrant et al produced a monospecific polyclonal antiserum through affinity purifying the antibody by column chromatography (see page 648, "Production and purification of rat anti-C14 ID antibody preparation"). The anti-Id antibody presented a positional isomer of the Lewis b hapten; the anti-ID presented the Lewis b antigen equally as well as Lewis y (see Durrant et al, page 654, first paragraph). Durrant et al still anticipates the instantly claimed invention as now claimed.

1. Since the Office does not have the facilities for examining and comparing applicant's protein with the protein of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same functional characteristics of the claimed protein). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594

2. Inherently the reference anticipates the now claimed invention. Atlas Powder Co. V IRECA, 51 USPQ2d 1943, (FED Cir. 1999) states Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art...However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior arts functioning, does not render the old composition patentably new to the discoverer. The Court further held that Athis same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art.

New Claim Limitations/New Grounds of Rejection

Claim Objections

3. Claims 5, 8, 16 and 19 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is

required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 5 and 8 recite the term "or homologues thereof", which broadens the scope of claims 3 or 4 or 6 from which they depend, in light of the amendments of claims 3-4 and 6 to recite the phrase "is not a HopA, HopB, HopC (HipC), HopD or HopE protein."

4. With the recitation of "or homologues thereof", the claimed immunoglobulin or antibody compositions may encompass the species of HopA, HopB, HopC (HipC), HopD or HopE or any of the 31 proteins that share the conserved sequences at the C-terminal or N-terminal which are homologues of H.pylori (see Bina et al, reference of record, abstract, and Figure 3 "DGVY" page 2375, col. 1 "We have done amphipathicity profiles on all 32 proteins related to HopE. These proteins share 40-60% identity in the conserved regions of the proteins"). Previously, Cover (Crisp document 5r01dk053623) was cited to show BabA to be a member of the Hop family of H.pylori outer membrane proteins. Also Pride et al (2001) was previously cited to show homology between Hop, BabA and BabB coding sequences (see page 1164, Figure 1). Therefore, Claims 5 and 8 broaden the scope of the claims from which they depend.

5. Claim 16 depends from claim 3, but comprises the same components presented in claim 3, with an amended recited intended use; claim 16 is not further limiting of claim 3.

6. Claim 19 depends from claim 6, with an amended recited intended use but comprises the same components presented in claim 6; claim 19 is not further limiting of claim 6.

7. Claims 4-8, 19 and 29-30 are objected to because of the following informalities:

8. Claims 6 and 19 have been amended to recite the term "nonospecific"; this is a misspelled word.

9. Claims 6 and 19 also have been amended to recite "HipC"; this is a misspelled term. The instant Specification does not provide a definition for HipC; it should be HopC.

10. Claims 4-5, 7-8 and 29-30 should recite ---The isolated----- to correspond to the amended claimed inventions from which the dependent claims depend.

11. Appropriate correction is required.

Claim Rejections - 35 USC § 112

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 3-5 and 6-8, 16, 19, 27-30 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The written description in this case sets forth nucleic acid and amino acid sequences for BabA and BabB (SEQ ID Nos 1-8) and therefore the written description is not commensurate in scope with the claims drawn to monospecific immunoglobulin compositions and antibodies that bind to proteins that comprise homologous amino acid sequences of SEQ ID NO 5, and comprise the homologous sequence and are not BabA or B of Helicobacter pylori, wherein the homologous proteins need not share any specific level of identity with the amino acid sequence set forth as SEQ ID NOs: 5, the overall size of the homologous protein that comprises the homologous amino acid sequence of

Seq ID NO 5, not being defined in the claims.

14. The specification does not provide written descriptive support for the claimed invention of ""homologues thereof" of SEQ ID NO 5, and the claimed invention being directed to antibodies that bind to the homologues. Thus, the structure of naturally occurring homologue sequences are not defined in the instant Specification, nor the claims, with the exception of BabA and BabB of Helicobacter pylori. The skilled artisan cannot envision the detailed structure of the polypeptide or a recombinant polypeptide that would induce a monospecific antibody or immunoglobulin composition that is now claimed and is a homologue of a protein that comprises the homologue of SEQ ID NO 5. Therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Description of a genus of immunoglobulins or antibodies that will bind to protein homologues of the amino acid sequence SEQ ID NO 5 (recited in claims 5 and 8) and no specific biological activity being required for the homologue, does not describe, nor enable a highly variable genus of antibodies or immunoglobulins that would bind the homologue polypeptides that shares a common homologous amino acid sequence and no common biological function.

The instantly claimed invention has not been so described by written description in order to enable the full scope of the invention because the claimed subject matter was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the

inventor(s), at the time the application was filed, had possession of the claimed invention. The instant specification does not provide guidance, teaching and suggestion as to where changes can be made that would result in a homologue protein that comprises a homologous amino acid sequence to SEQ Id No 5 in such a way that the instant Specification describes compositions of monospecific antibodies directed to the homologous proteins/polypeptide at the time the instant Application was filed.

However, no disclosure, beyond the mere mention of naturally occurring homologues (is made in the specification and what is now claimed are antibodies directed to the homologues, the structure not being defined by any specific structure correlated with function, the claimed immunoglobulin compositions and antibodies binding to the homologue protein not described. There is insufficient support for the generic claims as provided by the Interim Written Description Guide lines published in the June 15, 1998 Federal Register at Volume 63, Number 114, pages 32639-32645 and the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999.

15. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

16. Claims 5 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 5 and 8 encompass immunoglobulin compositions and

antibodies that are include antibodies to BabA protein and homologues of BabA protein based upon the recitation of the phrase "or homologues thereof".

17. The binding specificity of the homologues thereof is not defined to be that of BabA,. The combination of claim limitations directed to a "monospecific" immunoglobulin or antibody composition that binds to Lewis B antigen and also comprises homologues that may or may not bind to Lewis B antigen sets forth a combination of claim limitations that are contradictory to the recitation of there term "monospecific", to the binding specificity being that of Lewis B antigen and the recitation of the negative limitations of "not a HopA, HopB, HopC (HipC), HopD or HopE protein" because a composition that comprises antibodies that will bind to Lewis B binding antigen and to a homologue protein of BabA, would include Hop porin proteins in view of Bina et al (reference of record) that teaches a family of 31-32 outer membrane proteins (see abstract, first sentence) of Helicobacter pylori that share a conserved amino acid sequence that are defined by a conserved homologous amino acid sequence in each of the outer membrane proteins at the N-terminal. The homologous proteins evidence homology with SEQ ID NO 5 (see Bina et al, page 2372, col. 1, paragraph 4) .

EDDGFYTSVGYQ (subsequence of instant SEQ ID NO 5)

E*DG*Y****Y (homologue sequence of HopE, shared with SEQ ID NO 5).

Even though HopE is supposedly excluded from the claims, the recitation of the phrase "homologues thereof" adds back the excluded species. Additionally there are at least 25 other species (Bina et al, abstract teaches there are about 31 members of the outer membrane protein family of Helicobacter pylori) of homologue outer membrane protein that are encompassed by the recitation of the term "homologues thereof (plural tense)". A composition of antibodies

would not be monospecific it comprises antibodies directed to BabA and homologues thereof, because the antibodies that would bind to BabA would not necessarily bind to the homologue proteins, and the claimed antibodies/immunologulins are not required to bind only the epitopes held in common among the homologues that comprise a homologous amino acid sequence to SEQ ID NO 5, but may be proteins of diverse biochemical structures and functions from BabA, to include proteins such as HopA, Omp2, Omp29, HopZ or HopY or other membrane proteins with the recited conserved amino acid sequence that is a homologue of SEQ ID NO 5. Therefore the combination of claim limitations "monospecific" and "homologues thereof" set forth a combination of claim limitations that are not internally consistent with the meaning of the term "monospecific" and "homologues".

Double Patenting

18. (New Claims) Applicant is advised that should claims 27 and 29; and claims 28 and 30 be found allowable, claims 29 and 30 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof claims 27 and 28, respectively. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 102

Please Note: The following prior art rejection is being made of record in light of the claims having been amended to recite "monospecific" and the claimed antibodies are Not required to bind to BabA via the antibodies hypervariable region, but must only specifically bind to BabA. Human colostrum sIgA antibodies present the specific structural confirmation for Lewis b

antigen which specifically binds to BabA, in light of the evidence provided by Boren et al (1995, page 32) that Lewis B antigen is an essential part of the mucosal cell surface architecture and human colostrums which presents Lewis B carbohydrate antigen serves to provide protection against infection as it is a type of mimic receptor for inhibiting or preventing bacterial colonization.

19. Claims 3-8, 16,19, 27-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Uemura et al (US Pat 5,258,177) in light of evidence provided by Boren et al (1995, reference of record) .

Uemura et al (US Pat 5,258,177) disclose the instantly claimed isolated monospecific (see col. 2, lines 51-56) immunoglobulin compositions, the compositions comprising human secretory sIgA obtained from human colostrum (see col. 1, line 19; Uemura et al, claim 1). The purified sIgA was produced by chromatographic procedures (see col. 4, 14-20 and col. 8, claim 6) resulting in a composition of IgA that does not contain IgG and IgM, through the recitation of 0% IgG and 0% IgM (see claim 1), therefore claiming a monospecific composition of IgA.

In light of Applicant's definition including secretory human IgA colostrums ([paragraphs 0030; 0035; 0047 : IgA, human, polyclonal, milk]) which will specifically bind to Lewis-B binding adhesion protein of Helicobacter pylori, the monospecific compositions of Uemura et al obtained from human colostrums defined to be sIgA, inherently anticipates the instantly claimed invention in light of evidence provided by Boren et al (1995, reference of record, page 32, col. 1-2) who show human colostrum IgA to specifically bind to Helicobacter pylori blood group binding antigen (Bab, Lewis b antigen being present on the surface of sIgA of human colostrum). Inherently the reference anticipates the now claimed invention. Atlas Powder Co. V IRECA, 51 USPQ2d 1943, (FED Cir. 1999) states Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art...However, the discovery of a previously

unappreciated property of a prior art composition, or of a scientific explanation for the prior arts functioning, does not render the old composition patentably new to the discoverer. The Court further held that this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art.

Claim Rejections - 35 USC § 103

20. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

21. Claim 2 is rejected under 35 U.S.C. 103(a) as being obvious over Boren et al (reference of record, 1995) in view of Foster et al (US Pat. 4,444, 879, refernce of record.) .

Boren et al teach, show and provides guidance for the artisan to detect the presence of an Helicobacter pylori blood group binding protein antigen utilizing binding of colostrums sIgA in a method of detecting the presence or absence of the blood group antigen in the sample but differs from the instantly claimed invention by failing to show the incorporation of the IgA immunoglobulin/antibody into kit form.

Foster et al teach the formulation of immunoglobulin/antibody compositions into kit form in an analogous art for the configuring a product for distribution for medical purposes .

It would have been obvious to the person of ordinary skill in the art at the time the invention was made modify the configured composition of Boren et al into kit form as taught by Foster et al because Foster et al teaches kits that comprise immunoglobulin (see Foster et al, col.

15, lines 24-26) preparations and the kit provides immunoglobulin reagents for medical purposes (see Foster et al, col. 5, lines 63-68 and col. 6, lines 1-5).

In the absence of a showing of unexpected results, the person of ordinary skill in the art would have been motivated by the reasonable expectation of success of obtaining kits that comprise a human colostrums IgA immunoglobulin composition that is a monospecific that will bind to Helicobacter pylori BabA antigen because Boren et al teach and show the blood group binding protein to be associated with infection in human gastric mucosa (see figure top of page 32 "adhesion experiments), which was significantly inhibited through binding of secretory IgA isolated from human colostrums. The colostrums IgA eliminated H.pylori attachment to gastric surface mucous cells (see page 32, col. 1, paragraph 3) and was also utilized in determining the presence or absence of Helicobacter pylori in a human tissue sample (see page 32, col. 1, paragraph 1 "Immunohistochemical analyses") in an Helicobacter pylori immunoassay

Boren et al defines and shows colostrums sIgA as a specific Helicobacter pylori BabA detection reagent and Foster et al teach the importance of formulation of test kits that comprise the necessary reagents so the kits can be readily used by the medical community in detecting/diagnosing the presence or absence of a protein analyte in a biological sample, and Boren et al teaches BabA to be an Helicobacter pylori infection associated protein of the human pathogen. Boren et al in view of Foster et al obviate the instantly claimed invention.

Conclusion

22. This is a non-final action.

23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vgp
March 1st, 2006

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